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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,667	10/18/2001	James R. Prudent	FORS-06638	7631

23535 7590 08/28/2003
MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637 9

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,667	PRUDENT ET AL.	
	Examiner Jeffrey Siew	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 January 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 26-35,42 and 61-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 26-35,42 and 61-76 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 October 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 8 is acknowledged. The response has not submitted any traversal to the restriction and has cancelled claims that were drawn to Group II. The pending claims are 26-35,42,61-76.

Information Disclosure Statement

2. The information disclosure statement filed 1/22/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Priority

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. **If a parent application**

has become a patent, the expression “now Patent No. _____” should follow the filing date of the parent application. If a parent application has become abandoned, the expression⁷“now abandoned” should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was

unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-35,42,61-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6,348,314 in view of Eckert (NAR vol. 18 No. 13 pp. 3739-3743 1990).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 26-35,42,61-76 of the instant application are drawn to method for detecting presence of target nucleic acid comprising forming a cleavage structure with a synthetic target and cleaving with a thermostable 5' nuclease.

Claims 1-72 of US6,348,314 are drawn to the method of detecting the presence of target nucleic acid comprising forming a cleavage structure. Moreover, claim 14 of US6,348,314 are further drawn to thermostable 5' nuclease.

Claims 1-72 of US 6,348,314 do not recite synthetic.

Eckert teach a method of PCR synthesizing target nucleic acids of interest.

One of ordinary skill in the art would have been motivated to apply Eckert teaching of PCR synthesis to the method claims of US6,348,314 in order to selectively amplify target nucleic acid. It would have been prima facie obvious to apply Mullis PCR synthesis to method of detecting target sequence in order to selectively increase the target nucleic acid for detection.

5. Claims 26-29,33,42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 32 of U.S. Patent No. 5,846,717 in view of Eckert (NAR vol. 18 No. 13 pp. 3739-3743 1990)

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 26-29,33,42 of the instant application are drawn to method for detecting presence of target nucleic acid comprising forming a cleavage structure with a synthetic target and cleaving with a thermostable 5' nuclease.

Claims 1-32 of US5,846,717 are drawn to the method of detecting the presence of target nucleic acid comprising forming a cleavage structure. Moreover, claim 25 of US5,846,717 are further drawn to thermostable 5' nuclease.

Claims 1-32 of US5,846,717 do not recite synthetic.

Eckert et al teach a method of PCR synthesizing target nucleic acids of interest.

One of ordinary skill in the art would have been motivated to apply Eckert et al teaching of PCR synthesis to the method claims of US5,846,717 in order to selectively amplify target

nucleic acid. It would have been *prima facie* obvious to apply Eckert et al's PCR synthesis to method of detecting target sequence in order to selectively increase the target nucleic acid for detection.

6. Claims 26-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,001,567 in view of Eckert (NAR vol. 18 No. 13 pp. 3739-3743 1990).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 26-29 of the instant application are drawn to method for detecting presence of target nucleic acid comprising forming a cleavage structure with a synthetic target and cleaving with a thermostable 5' nuclease.

Claims 1-15 of 6,001,567 are drawn to the method of detecting the presence of target nucleic acid comprising forming a cleavage structure. Moreover, claim 5 of US6,001,567 is further drawn to thermostable 5' nuclease.

Claims 1-15 of 6,001,567 do not recite synthetic.

Eckert et al teach a method of PCR synthesizing target nucleic acids of interest.

One of ordinary skill in the art would have been motivated to apply Eckert et al's teaching of PCR synthesis to the method claims of US6,001,567 in order to selectively amplify target nucleic acid. It would have been *prima facie* obvious to apply Eckert et al's PCR synthesis to method of detecting target sequence in order to selectively increase the target nucleic acid for detection.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-35,42,61-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 26-35,42,61-76 are indefinite because the language in claim 26 does not clearly describe the cleavage structure formed. The claim recites that the second nucleic acid has 5' portion that is completely complementary to second portion. It is unclear as to whether the 5' is hybridized partially or fully or at all to the region. Similarly the language of the first nucleic acid is unclear.

B) The term "synthetic" in claim 26 renders claims 26-35,42,61-76 indefinite. It is unclear as to whether the scope of term refers to fragments manually constructed through a oligonucleotide synthesizer or fragments derived from biological sources that have been processed through the intervention of person's hand e.g. restriction digestion, sonication, nebulization etc. Or whether the term refers to PCR synthesized nucleic acid.

SUMMARY

8. No claims allowed.

CONCLUSION

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER

August 25, 2003